

BEST AVAILABLE COPY

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
25 May 2001 (25.05.2001)

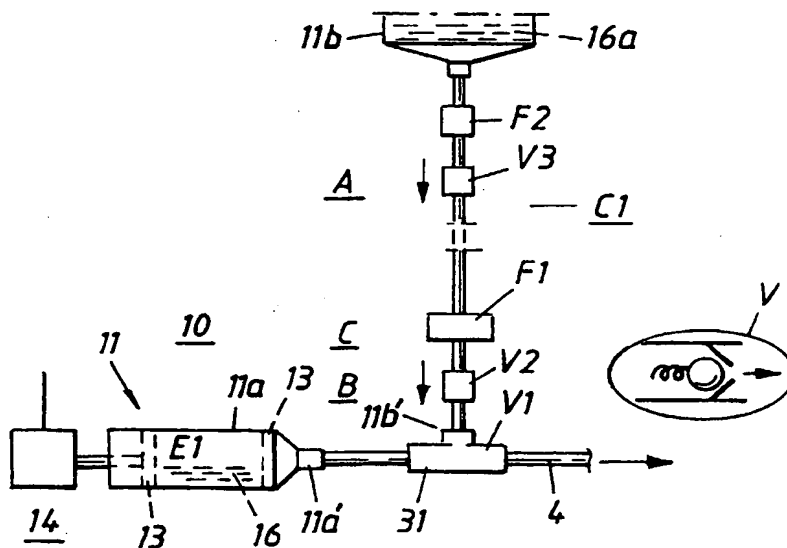
PCT

(10) International Publication Number
WO 01/36026 A1

- (51) International Patent Classification⁷: A61M 5/14, 5/00
- (21) International Application Number: PCT/SE00/02222
- (22) International Filing Date:
13 November 2000 (13.11.2000)
- (25) Filing Language: Swedish
- (26) Publication Language: English
- (30) Priority Data:
9904123-8 15 November 1999 (15.11.1999) SE
- (71) Applicant (for all designated States except US): ANEO AB [SE/SE]; Maskingatan 3, S-195 60 Märsta (SE).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): JAKOBSSON, Jan, Gustav [SE/SE]; Falks väg 13, S-182 54 Djursholm (SE). STRÖMBERG, Stefan, Per, Axel [SE/SE]; Albods väg 18, S-193 40 Sigtuna (SE).
- (74) Agents: KARLSSON, Leif et al.; L.A. Groth & Co. KB, P.O. Box 6107, S-102 32 Stockholm (SE).
- (81) Designated States (national): AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— With international search report.

[Continued on next page]

(54) Title: A SYSTEM RELATED TO INTRAVENOUS ANAESTHESIA



(57) Abstract: The invention shows that conditions can be created in intravenous anaesthesia in which single-patient parts and accessories are separated from multi-patient parts and accessories by utilisation of a filter preventing contaminating particles from migrating from single-patient parts and accessories to multi-patient parts and accessories.

WO 01/36026 A1



— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

A SYSTEM RELATED TO INTRAVENOUS ANAESTHESIA

Field of invention

The present invention relates to a system in intravenous anaesthesia and,
5 more particularly, to a system for use in intravenous anaesthesia for adjustable delivery of fluid medication to a patient to be anaesthetised..

The present invention relates more particularly to a system comprising at least one container for the said fluid medication, a circuit for regulating the volume of medication supplied to the said patient per unit of time and a tube between the
10 said container and the said patient.

The following description utilises the term "patient". "Patient" refers both to a person and to different animals requiring anaesthesia for surgical procedures.

Prior art

15 Intravenous administration of a parenteral nutritional support solution, or a liquid comparable to a parenteral nutritional support solution, with a catheter, needle or cannula introduced into a vein, and connection of a tube between this cannula and a container holding the said parenteral solution, such as a saline solution or the like, positioned at a higher level than the patient, are previously known. In
20 these applications, the container is normally hung on a stand.

A valve arrangement, through which the volume of fluid can be adjusted with different settings producing different tube choking, i.e. the volume of fluid administered per unit of time can be adjusted, is attached to the tube.

25 Arrangements of this kind are patient-related. This means that the container, tube, valve arrangement etc. which are relatively inexpensive, are discarded after the fluid has been administered, and no stringent demands are made on the accuracy of the rate of fluid administration. The pressure of fluid in the tube and cannula will depend on the height of the fluid container above the level of the patient.

30 No extreme demands are made on cleanliness, because the total amount of fluid in the container is selected and intended for only one patient and because the empty container with its associated valve arrangement and tube is discarded after infusion of the parenteral nutritional support solution or the like.

However, when intravenous anaesthesia is involved, greater demands must be made on accuracy in the rate of medication infusion, time-related variations in the rate set, the volume delivered and cleanliness.

In intravenous anaesthesia, the field to which the present invention relates, an anaesthesia-inducing drug is intravenously supplied to the patient, usually in large amounts during an initial phase in order to induce a desired depth of anaesthesia in the patient, followed by smaller amounts to keep the patient within suitable limits for the desired depth of anaesthesia.

Medication required for this purpose is supplied in containers holding standard volumes, concentrations etc. So estimating the time required for the suitable state of anaesthesia and the desired of anaesthesia and selecting a medication container volume, based on patient-related criteria (age, sex, race, weight etc.), corresponding to the time required to perform a surgical procedure, are also known.

However, such estimates have proved to be very rough, as every surgical procedure is unique and duration is difficult to determine in advance.

If an operation takes less time than estimated, too much medication could be left in the container and tube, i.e. a residual volume, which must be discarded. If an operation lasts longer than estimated, an empty medication container will have to be replaced with a new, full container.

This replacement of an empty container with a full one is an inconvenient circumstance during a surgical procedure, not the least because of the risk of erroneous connection, and the normal tendency is to start with a container whose volume of medication is excessive, thereby obviously increasing residual volume at the end of the surgical procedure.

If the selected volume still proves to be inadequate, the used, empty container must be replaced with a full container. Experience has shown that the excessive amounts of medication in the new container contributes to residual volume which must be discarded.

These containers are normally placed in an infusion unit in which the volume of medication infused per unit of time is regulated, making the replacement of an empty container with a full one a time-consuming step.

Analgesics and/or muscle relaxants are also commonly used in conjunction with the induction of anaesthesia with intravenous infusion of hypnotics and soporifics.

Containers, tubes etc. are also all devised for use with a single patient.

5 The risk of contamination is deemed to be too great for utilisation of one medication container with a plurality of patients, as bacteria, viruses and similar particles from a first patient could migrate up through the tube into medication in the container and be passed on to subsequent patients.

10 Medication contaminated in this way could then be supplied to a second, third, fourth patient etc. through use of the same cannula and/or the same container.

15 Different systems and devices for adjustable regulation of the administration of a fluid anaesthetic to a patient to be anaesthetised are previously known. An infusion unit pump, which by means of positive pressure in a container (a syringe arrangement), is used here to force medication through the tube and a cannula to a patient.

20 This application makes major demands on highly adjustable and accurately regulated administration of medication per unit of time and major demands on the control of this process, control being dependent upon detectable patient-related criteria.

25 The simplest embodiment of such a system for intravenous anaesthesia comprises at least one container for holding the said fluid medication, a circuit for regulating the volume of medication supplied to the patient per unit of time and a tube, between the said container or the said circuit and the said patient, one end of which being attached to a cannula inserted into a vein or the like.

 The container, with tube and a valve arrangement, is normally conjoined into a single unit and can be located in an infusion unit containing a pump controlled by a control unit connected to the infusion unit.

30 This known arrangement is illustrated in greater detail in the following description of the embodiment shown in fig. 2.

 Utilisation of an infusion unit, with an associated control unit, in which the control unit is devised to controllably drive a stepper motor connected to a piston in a syringe on the basis of patient-related and other parameters in order to regulate and evaluate the amount of medication supplied per unit of time and the total

amount of medication supplied, depending on the stepper motor's movements, is previously known.

The invention is therefore primarily devised for use in anaesthesia, more particularly in intravenous anaesthesia.

5 The present invention accordingly relates to and comprises a system permitting the infusion of a volume of fluid anaesthetic-inducing medication per unit of time into the blood of a living creature or a patient.

Here, the use of a lung ventilator and a monitoring and infusion unit, in which the latter, controlled by a control unit, is able to induce a depth of anaesthesia in the patient within limits selected for the depth of anaesthesia, is a practical
10 necessity.

Description of the present invention

Technical problems

15 If the circumstance that the technical aspects someone well-versed in the art needs to consider in solving one or more technical problems is taken into account, insight is initially required into the steps and/or the sequence of steps which need to be taken and a choice of the requisite means. On the basis thereof, the following technical problems should be relevant in achieving the present invention.

20 With a view to the prior art as described above, creating conditions, using simple means, in which the volume of residual medication remaining after concluded surgery and conclusion of intravenous anaesthesia is kept to a minimum, largely irrespective of the duration of the state of anaesthesia, should be regarded as a technical problem.

25 Creating conditions, using simple means, enabling certain parts and accessories to be devised for single-patient use and for a small residual volume and other parts and accessories to be devised for multi-patient use without migration of contaminating particles from single-patient parts and accessories to multi-patient parts and accessories, is another technical problem.

30 Creating, using simple means, a distinct and readily distinguishable interface between parts and accessories for multi-patient use and parts and accessories for single-patient use and preventing contaminating particles from migrating from the former to the latter should also be regarded as a technical problem.

Here, creating conditions, using simple means, enabling a depleted container for an anaesthesia-inducing drug to be refilled primarily with small amounts during the anaesthesia in an effort to keep residual volume low, especially at the end of anaesthesia, is a technical problem.

5 Being able to realise the importance of creating conditions in this technical field enabling a connection arrangement and/or some other and/or some additional connection arrangement, installed in the direction of flow, to be devised to prevent small contaminating particles from migrating into the said container during a normal flow of medication in one direction is a technical problem. The said connection
10 arrangement is to be positioned so the residual volume is small.

 Being able to realise the importance of subdividing a large-volume container into at least two parts, i.e. one part being a container (e.g. a syringe, pump or the like) holding a small volume of medication in the infusion unit and one part being a reserve container, directly or indirectly connected to the said container,
15 holding a larger volume of medication, is a technical problem.

 Being able to realise the importance and advantages of providing the infusion unit's container with a connector for medication refilling is also a technical problem. This connection must be located adjacent to or consist of a container outlet for medication.

20 Being able to realise the importance and advantages of devising an infusion unit control unit so it first empties the contents of the infusion unit container and then transfers small amounts of anaesthesia-inducing medication to the said container from a reserve container, thereby keeping residual volume small, is also a technical problem.

25 Being able to realise the importance of interposing a valve arrangement, comprising e.g. a one-way valve, between the container and the reserve container is a technical problem.

 Being able to realise the importance and advantages of arranging a filter, using simple means, in or adjacent to the connection arrangement, to prevent contaminating particles from crossing the interface between multi-patient parts and accessories and single-patient parts and accessories is also a technical problem.
30

 Creating conditions, using simple means, permitting continuous administration of medication to the patient, although not by means of a continuous flow of fluid or medication, is also a technical problem

Being able to realise the importance and advantages of equipping the said filter with a means for shutting off the continuous flow of medication is an additional technical problem.

5 Being able to realise the importance and advantages of arranging a filter, devised to keep bacteria, viruses and similar contaminating particles from reaching medication in the reserve container, between a container and a reserve container, thereby making possible the use of medication in the reserve container as a supplementary volume for use with a plurality of different people or patients, is an additional technical problem.

10 Being able to realise the importance and advantages of arranging a shut-off valve between the reserve container and the connection arrangement is also a technical problem.

Within the scope of the invention, a selected container and/or reserve container can consist of a rigid container, or both the container and/or the reserve
15 container can consist of a flexible container.

Providing the said connection arrangement with a common arrangement for transferring medication from and sending air to the reserve container, especially when the reserve container is a rigid container, is a technical problem.

20 Being able to realise the importance and advantages of having a dual-passage filter or connection arrangement, i.e. with one medication passage and one air passage separated from each other, a filter for impeding airborne bacteria, viruses and other contaminating particles being arranged in the air passage, is also a technical problem.

25 Being able to realise the importance and advantages of using an infusion unit container with a first volume corresponding to the volume required during an initial phase of anaesthesia in order to induce a desired depth of anaesthesia in the patient is an additional technical problem. After the initial phase, the infusion unit is devised to supply the patient, with a smaller volume of medication per unit of time in order to keep the patient within suitable limits for a desired of anaesthesia.
30

Being able to realise the importance of utilising a three-way connector, connected to the container, the reserve container and patient tube, with one-way valves in a line to the reserve container and tube, a one-way valve for the reserve container being devised to permit the passage of medication only at a pressure

exceeding a pre-selected value somewhat greater than hydrostatic pressure from the reserve container is an additional technical problem.

Technical considerations are involved and technical problems must be resolved in realising that a filter must be arranged, upstream and/or downstream
5 from a one-way filter, and/or that a one-way filter can be arranged upstream and/or downstream from the said filter.

Being able to realise the importance and advantages of conjoining a one-way valve and a filter and locating them close to each other is a technical problem. An interface can also be arranged between the three-way connector and the one-
10 way valve. As an alternative, the said interface can be arranged upstream from the filter, preferably close to the reserve container.

Being able to realise the importance and advantages of using an infusion unit container, with a second volume less than a first volume, devised for initially inducing a desired depth of anaesthesia in the patient by means of a selected
15 number of emptyings and refillings of the said second volume, the infusion unit being devised to deliver a smaller amount of medication per unit of time after the initial phase in order to keep the patient within suitable limits for the desired depth of anaesthesia, is a technical problem.

Being able to realise the importance and advantages of connecting the
20 tube to the filter and having the interface downstream and/or downstream from the said filter is a technical problem.

Being able to realise the importance and advantages of having the regulatory circuit consist of e.g. a piston-cylinder arrangement with one-way valves on either side, the reciprocal motion of the piston being controlled by a control circuit in
25 the infusion unit, thereby providing an opportunity for conjoining the said piston-cylinder arrangement and the said one-way valves in a single unit whose external shape is devised to fit the shape of a recess for an infusion unit container, a filter being provided upstream and/or downstream from the said unit, the said interface being provided downstream and/or upstream from the said filter, is a technical
30 problem.

Being able to realise the importance and advantages of arranging the tube between a container with a large volume, through one or more filters and a medication-regulating circuit, and a cannula or the like, is a technical problem.

Being able to realise the importance and advantages of devising the said circuit choke off and/or open the tube cross-section, using a plate or similar peripheral part of the control unit, in order to regulate the supply of medication, the said filter being arranged downstream and/or upstream from the said circuit, is a technical problem.

Being able to realise the importance and advantages of devising the medication-regulating circuit to control the supply of medication solely on the basis of patient-related criteria, the supply of medication being arranged to be provided from a container above the level of the patient, is a technical problem.

Being able to realise the importance and advantages of devising the said circuit to choke off and/or open the tube cross-section by means of a pump or a similar peripheral part of the control unit in order to regulate the supply of medication is a technical problem. One or more filters can then be arranged downstream and/or upstream from the said pumping unit, an interface being arranged downstream and/or upstream from a filter.

Solution

The present invention is based on a system for adapting the administration of fluid medication, in intravenous anaesthesia, to a patient to be anaesthetised, the said system thereby comprising at least one container to hold the said fluid medication, a circuit for regulating the volume of medication delivered to the said patient per unit of time and a tube between the said circuit and/or container to the said patient, a connection arrangement being provided between the said container and the said tube and arranged to enable medication to flow from the said circuit and/or container through the said tube to the patient.

In order to solve one or more of the aforementioned technical problems, the present invention shows that the connection arrangement can consist of a filter devised to separate multi-patient parts and accessories from single-patient parts and accessories, and the said filter forms an interface preventing contaminating particles from migrating to the former parts and accessories.

As a further refinement of the invention concept, one connection arrangement and/or another and/or some additional connection arrangement arranged in the direction of flow is/are devised to prevent the passage of small contaminating particles to the said container during the normal flow of medication in

one direction, and the connection arrangement is arranged to keep residual volume small.

With a system of the kind described above, the present invention also sets forth, as ideas for future lines of development, subdivision of the container into at least two parts, i.e. one part being a container in an infusion unit and one part being a reserve container connected to the said container.

In addition, the present invention shows that the infusion unit container has a medication filler connector located near an outlet or consists of a medication outlet.

In addition, the present invention shows that the infusion unit's control unit is devised and controllable so it first empties the contents of the infusion unit container and then sequentially transfers small amounts of medication from the reserve container, thereby keeping residual volume small.

The invention also shows that a valve arrangement, comprising at least one one-way valve, is arranged between the container and the reserve container.

In addition, the present invention shows that the said filter, devised to block the migration of bacteria, viruses and similar contaminating particles into medication held in the reserve container, is arranged between the container and the reserve container.

A valve can also be arranged between the reserve container and the connection arrangement.

The reserve container and/or the container can consist of a rigid container (flask) or, more advantageously, a flexible container (bag). With a rigid container, the said connection arrangement must have an arrangement for sending air to the reserve container.

This shows that the connection arrangement must have two parts, i.e. one passage for medication and one passage for air, a filter being arranged in the air passage to block the passage of airborne bacteria, viruses and similar contaminating particles.

The invention sets forth that the infusion unit container shall have a first volume corresponding to the amount of medication required in order to induce a desired depth of anaesthesia during an initial phase.

The infusion unit is devised to supply the patient with smaller amounts of medication per unit of time, after the initial phase, in order keep the patient within

appropriate limits for the desired depth of anaesthesia and achieve small residual volumes.

A three-way connector is connected to the container, reserve container and patient tube with one-way valves arranged in a line to the reserve container and tube.

The reserve container's one-way valve is devised to permit the passage of medication only at a pressure exceeding a pre-selected value, i.e. somewhat higher than hydrostatic pressure from the reserve container.

A filter can advantageously be arranged upstream from the said one-way valve, and a one-way valve can advantageously be arranged upstream from the said filter.

A shut-off and/or opening valve can be arranged upstream from the said one-way valve.

A one-way valve and a filter can be interconnected near each other.

Here, the said interface can be arranged between the three-way connector and the one-way valve.

The said interface can therefore be arranged upstream from the filter, and/or the interface can be arranged next to the reserve container.

A container for an infusion unit can have a second volume, smaller than the said first volume, devised for initially inducing a desired depth of anaesthesia with a selected number of emptyings and refillings of the said second volume during an initial phase.

The infusion unit is devised to deliver, after the initial phase, a smaller amount of medication per unit of time to the patient in order to keep the patient within appropriate limits for the desired depth of anaesthesia.

Here, the tube can be connected to the filter, and the interface can be arranged downstream and/or upstream from the said filter.

The regulatory circuit can consist of a piston-cylinder arrangement or the like with a one-way valve on either side, the piston's reciprocal movement being controlled by a control circuit in an infusion unit.

The said piston-cylinder arrangement and the said one-way valves are conjoined into a physical unit whose external shape can be made to fit exactly into an infusion unit recess intended and devised for a container.

The invention also shows that a filter is arranged upstream from the said unit, and the said interface is arranged downstream and/or upstream from the said filter.

A tube can be arranged between a container with a large volume, through
5 one or more filters, past a medication-regulating circuit and a cannula or the like.

Here, the said circuit is devised to choke off and/or open a section of tube, by the action of a control unit plate or the like on the periphery of the tube, in order to regulate the supply of medication.

The said filter is arranged downstream and/or upstream from the said circuit, and the said interface can be arranged downstream and/or upstream from the
10 said filter.

The medication-regulating circuit is devised to control the delivery of medication solely on the basis of patient-related criteria, the delivery of medication being advantageously arranged for provision from a container above the level of
15 the patient.

The said circuit is also devised to choke off and/or open a section of tube, by the action of a pump or a control unit on the periphery of the tube, in order to regulate the supply of medication.

Here, the invention proposes that one or more filters be arranged downstream and/or upstream from the said pumping unit.
20

The said interface can then be arranged downstream and/or upstream from one or more filters.

The medication-regulating circuit can also be arranged to control the delivery of medication on the basis of patient-related criteria, the volume of medication supplied etc., although only taking into account information on the volume of
25 medication supplied per unit of time or the total volume supplied.

Even here, the delivery of medication can be devised to take place from a container above the level of the patient.

30 Advantages

The main advantages of a system according to the invention are that the system creates, using simple means, conditions for devising certain parts and accessories for multi-patient use while other parts are devised for single-patient use through the use of a connection arrangement, preferably in the form of a filter be-

tween them, single-patient parts and accessories being devised for small residual volumes, thereby limiting undesirable amounts of residual anaesthesia-inducing medication which would have to be thrown out.

This is achieved in practice by use of an infusion unit container whose
5 volume of medication is devised to be equal to or somewhat less than the volume likely to be needed for a suitable duration of anaesthesia, a desired depth of anaesthesia and other relevant criteria. If more medication should be needed, small amounts can be successively supplied from a reserve container, thereby creating conditions for keeping residual volume small at the end of anaesthesia.

10 This accordingly reduces the volume of medication which is normally removed and thrown out because the infusion unit's volume of medication is greatly over-dimensioned for safety reasons. A connection arrangement and filter simultaneously prevent contaminated medication from a patient from migrating into medication intended for one or more other patients.

15 The main significant feature in a system for regulating the supply of fluid medication to a patient in whom narcosis is to be induced by means of intravenous anaesthesia is set forth in the characterising part of patent claim 1.

Brief description of the figures

20 Two previously known systems for intravenous administration of fluids and medication to a patient, as well as a system set forth in the invention, will now be described in greater detail, referring to the attached drawings in which:

- Figure 1 illustrates the principle for intravenous administration of a parenteral nutritional support solution to a patient from a container in which the
25 fluid can consist of e.g. a saline solution;
- Figure 2 shows the principle parts of an infusion system for adjustable administration of medication to a person in intravenous anaesthesia;
- Figure. 3 illustrates the principles of a first embodiment according to the invention;
- 30 Figure 4 shows a longitudinal section of a proposed connection arrangement with a filter for a medication passage and an air passage;
- Figure 5 illustrates the principles of a second embodiment according to the invention;

- Figure 6 illustrates the principles of a third embodiment according to the invention;
- Figure 7 illustrates the principles of a fourth embodiment according to the invention;
- 5 Figure 8 illustrates the principles of a fifth embodiment according to the invention;
- Figure 9 is a time diagram illustrating variations in the amount of medication administered during anaesthesia.

10 **Description of prior art**

Fig. 1 is a drawing of a system for adjustable, limited-precision regulation of a parenteral nutritional support liquid, such as a saline solution, for intravenous administration to a person.

Fig. 1 shows a cannula 1 inserted into a vein 2 in an arm 3.

- 15 The cannula 1 is connected to a tube 4, one end 4a of which is connected to the said cannula 1 and the other end 4b is connected to a container 5, usually a flexible plastic container holding a fluid 6, e.g. a saline solution.

- Here, a valve arrangement 7 is attached to or arranged around the tube 4, and the volume of fluid administered per unit of time can be regulated by the ac-
- 20 tion of the valve arrangement 7 in the known manner.

It should be noted that no great accuracy is needed in the administration of fluid for this application. So a simple valve arrangement 7 can therefore be used when the amount of fluid administered per unit of time is not critical.

- In addition, large flows, e.g. up to 500 ml/hour or even more in some in-
- 25 stances, can be delivered with this valve arrangement.

A system for regulating the amount of fluid medication administered to a patient to be anaesthetised requires far greater precision.

- The process entails Initially administering a large flow and then greatly reducing the flow to an adjustable level, thereby achieving a desired depth of anaes-
- 30 thesia. This is illustrated in fig. 9.

Fig. 2 is a schematic rendition of a syringe 11 with a container 12, a piston 13 and a control unit 14, containing a stepper motor 15, in an infusion unit 10.

The system according to fig. 2 comprises at least one container 12 for fluid medication 16 and a regulatory circuit or control unit 14 for regulating administration of a volume of medication per unit of time to the said person.

In addition, a tube 4 is arranged between the said container 12 and the
5 said patient P.

A connection arrangement 17 between the said container 12 and the said tube 4 is arranged to enable medication 16 to flow from the said container 12, via the said control unit 14 and the said tube 4, to the patient P.

Fig. 2 shows that one tube end 4a is connected to a three-way connector
10 or the equivalent to enable one or more containers 11, 11' to be connected to the tube 4', one end of which is arranged for connection to the cannula 1.

Description of proposed embodiments

The invention is based on the experience that users commonly select a
15 much larger volume of medication 16 than the volume consumed during anaesthesia to avoid the need to replace an empty syringe 11 with a new one or refill an empty syringe with medication during surgery.

So large residual volumes remain and cannot be saved for use with another patient due to the risk of infection.

20 The invention is based on a system for regulated adaptation of the fluid medication administered to a patient to be anaesthetised during intravenous anaesthesia, the said system comprising at least one container to hold the said fluid medication, a regulatory circuit or control unit for regulating the volume of medication administered per unit of time and a tube between the said circuit or container
25 and the said patient, a connection arrangement being provided to permit the passage of medication from the said container to the patient.

A filter, linked to the connection arrangement, is devised to separate multi-patient parts and accessories from single-patient parts and accessories. The said filter forms an interface preventing contaminating particles from migrating to the
30 former parts and accessories.

This means that the volume of medication 16 can be somewhat less, by a wide margin, than the volume calculated as necessary for inducing anaesthesia, and a supplementary volume of medication can be sent to the syringe 11 from a reserve container 11a.

The container 11a and the reserve container 11b interact by means of a connection arrangement 31 which could contain valves (V1, V2) and a filter (F1).

The said connection arrangement 31 and/or some other and/or some additional connection arrangement with filters, arranged in the direction of flow, is
5 devised to prevent the migration of small contaminating particles to the said container 11b and/or container 11a during a normal flow of medication through the tube 4 in a given direction. The connection arrangement is arranged to ensure that residual volume is small.

Fig. 3 shows that the container 11 is divided into at least two parts 11a,
10 11b, one being a container or syringe 11a, holding a selected small volume of medication, in an infusion unit 10 and one being a reserve container 11b, holding a large volume of medication, connected to the said container 11a.

Here, the volume of medication for the container 11a can be selected for reasons other than the estimated duration of the surgical procedure and be much
15 smaller, as a sufficient reserve volume is available in the reserve container 11b.

The invention sets forth the use of one or more filters F, and this/these filter(s) separate(s) multi-patient parts and accessories A from single-patient parts and accessories B.

The filter F forms an interface C preventing contaminating particles from
20 migrating from single-patient parts B to multi-patient parts A.

Single patient parts and accessories B are devised to have a small residual volume at the end of anaesthesia. This means that e.g. the container 11a should then be virtually empty. Other parts and accessories are selected for a small residual volume.

25 Fig. 3 is a schematic depiction of a first embodiment with the features associated with the present invention.

The infusion unit's 10 container 11a has a connector 11b' through which medication can be filled, and the connector is arranged close to or consists of a medication outlet 11a'.

30 An infusion unit's 10 control unit 14 can be devised to empty the contents of the infusion unit's container 11a and then transfer small amounts of anaesthesia-inducing medication, as needed and successively, from the reserve container 11b to keep residual volume small in single-patient parts.

This can be achieved when a piston 13 performs reciprocal movements within the dashed range shown in fig. 3 in order to pump medication from the container 11b to the container 11a and from the container 11a, via a three-way connector 31 and the tube 4, to the patient.

5 The anaesthesia can now be concluded with a small residual volume because the container 11a is empty, and tubing has a small cross-section.

A number of valve arrangements V, each of which containing a one-way valve, is arranged between the container 11a and the reserve container 11b.

10 A first one-way valve V1 is built into or connected close to the said three-way connector 31, and a second one-way valve V2 is built into or close to the said three-way connector 31 path to the reserve container 11b.

The one-way valve V2 is connected to a first filter F1.

As an alternative, a filter F2 and a one-way valve V3 can be connected close to the reserve container 11b.

15 The filter F1 and one-way valve V2 can be omitted in certain applications. The selected interface is then moved to the position designated C1.

The filter F1 and/or the filter F2 are designed to block the access of bacteria, viruses and similar contaminating particles to medication 16a in the reserve container 11b.

20 The reserve container 11b and/or the container 11a can advantageously be flexible or rigid containers.

When a rigid container 11b is utilised, an arrangement is proposed for feeding air into the reserve container 11b as it empties of medication 16a.

25 There is nothing to prevent having an outlet for medication and an inlet for air.

Fig. 4 shows that a combined arrangement of this kind can be divided into two parts, i.e. with a passage 43 for medication and a passage 44 for air, and a filter 45 is arranged in the air passage to prevent bacteria, viruses and similar contaminating particles from passing from ambient air into the container 11b.

30 The medication passage 43 has an upper space 43a filled with medication 16a. This medication passes through a filtering unit 43b and, via a drip nozzle 43c in which drops traverse a gas-filled (air-filled) space 43d to a space 43e before passing through some additional filter F3 or a valve.

Fig. 3 also shows the use of an infusion unit's 10 container 11a with a first large volume 11a intended for rapidly inducing a desired depth of anaesthesia in an initial phase.

The infusion unit is also devised to deliver smaller amounts of medication per unit of time, after the initial stage, in order keep the patient within appropriate limits for the desired depth of anaesthesia.

Here, it should be noted that the amount of hypnotic proposed for administration during the initial phase t_0 to t_1 can be 10 to 30 ml administered over 3 to 4 minutes, e.g. 20 ml over 2 minutes. The amount supplied during the remaining time t_1 to t_2 can be 50 to 100 ml/ hour. The total volume administered during the anaesthesia can be 100 to 500 ml.

Here, it should be noted that the amount of analgesic proposed for administration during the initial phase t_0 to t_1 can be 1 to 2 ml. The amount administered during the remaining time can be 10 to 50 ml/hour.

Here, it should be noted that the amount of muscle relaxant proposed for administration during the initial phase t_0 to t_1 can be 3 to 5 ml. The amount administered during the remaining time can be 3 to 5 ml/hour.

It should be noted that each of the aforesaid agents requires a separate infusion unit and control unit.

Hypnotics can be advantageously administered sequentially. Long-acting analgesics can also be advantageously administered sequentially, whereas muscle relaxants can be administered continuously under controlled conditions.

A three-way connector 31 is connected to the container 11a, the reserve container 11b and the patient tube 4 by one-way valves in the line to the reserve container 11b and the tube 4. One or more filters can be built into the three-way connector 31.

The one-way valve (V2) for the reserve container 11b is devised to allow the passage of medication 16a only at a pressure, exceeding a pre-selected value, somewhat higher than hydrostatic pressure from the reserve container 11b.

A filter F1 is arranged upstream somewhat from the said one-way valve V2, and an additional one-way valve V3 is arranged upstream from the said filter F1.

A shut-off and/or opening valve (not shown) can be arranged upstream from the said one-way valve V3.

A one-way valve V2 (V3) and a filter F1 (F2) can advantageously be interconnected close to one another and form a single unit.

The interface C can advantageously be arranged between the three-way connector 31 and the one-way valve V2, but there is nothing to prevent arrangement of the interface upstream from the filter F1 and/or close to the reserve container 11b.

Fig. 5 shows an alternative to fig. 3 in which the infusion unit's 10 container 11a' has a second volume E2, much smaller than the first volume E1, the former being devised to deliver a desired depth of anaesthesia in the patient with a selected number of emptyings and fillings of the said second volume E2 during an initial phase.

It is proposed that the volume E2 be selected so 2-5 emptyings are needed for the delivery of a sufficient volume of medication during the initial phase.

The infusion unit is also devised to supply the patient, after the initial phase, with a smaller amount of medication per unit of time in order to keep the patient within appropriate limits for the desired depth of anaesthesia.

Fig. 6 shows an alternative embodiment in which the container 11a has been removed and medication is only supplied from one large container 11b.

Here, the tube 4 is connected to a filter F4 and/or F5, and one or more interfaces C2, C3, C4, C5 can be arranged downstream and/or upstream from the said filter.

Here, the regulatory circuit or control unit 14 consists of a piston-cylinder arrangement 61 with one-way valves V4, V5 on each side, the reciprocal movements of the piston being controlled by a control circuit 14 in the infusion unit.

The said piston-cylinder arrangement 61 and the said one-way valves V4, V5 are conjoined into a single unit 62 whose external shape fits the shape of an infusion unit recess devised to hold a container 11a.

Having the filter F4 arranged upstream from the said unit 62 may be important.

The said interface C2, C3 is arranged downstream and/or upstream from the said filter F4.

The embodiment according to fig. 7 shows that a single tube 4 is arranged between a large-volume container 11b, through one or more filters F6 and F7 respectively, a medication-regulating circuit 71 and a cannula or the like.

The said circuit 71 is devised to choke off and/or open the tube cross-section, by means of a plate 71a or the like, a stop 71b and a control unit's 14 stepper motor 15, in order to regulate the delivery of medication.

5 The said filters F6, F7 are arranged downstream and/or upstream from the said circuit, and one or more interfaces C6, C7, C8, C9 are arranged downstream and/or upstream from the said filters F6, F7.

The medication-regulating circuit or control circuit 14 is devised to control the delivery of medication solely on the basis of patient-related criteria. The amount of medication delivered and/or volume per unit of time can be estimated in
10 order to provide the surgeon with useful information but is not part of the control process. These amounts can be obtained from the control unit and the setting set for the stepper motor.

Patient-related criteria and the choice of same can be made in the manner shown and described in Swedish patent application no. 9901688-3, filed on 10
15 May 1999 and entitled "Arrangemang for att kunna tilldela en levande varelse ett anestesialt tillstånd" (i.e. Arrangement for inducing a state of anaesthesia in a living creature).

The contents of the said patent application shall be regarded as a part of this application.

20 Here, the administration of medication shall be devised to take place from a container 11b above the level of the patient.

Fig. 8 shows that the control unit 14 causes a medication-regulating circuit 14 with a stepper motor 15 to choke off and/or open the cross-section of a tube 4 by means of a pump (with a peristaltic action to force fluid or medication downstream) or similar unit 81 on the periphery of the tube in order to thereby regulate
25 the delivery of medication. A moving means 81a, acting against a fixed plate 81b, is arranged here.

Filters F8, F9 are arranged downstream and/or upstream from the said pumping unit 81, and the said interfaces, such as C10, C11, C12, C13, can be arranged downstream and/or upstream from the filter F8 and F9 respectively.
30

The medication-regulating circuit is primarily arranged for regulating the delivery of medication according to patient-related criteria and from information on the momentary amount of medication supplied per unit of time.

Fig. 9 shows, using a solid line, that a relatively large volume of medication is supplied during an initial phase t_0 to t_1 in order to quickly induce a state of anaesthesia in the patient. The desired depth of anaesthesia is illustrated with a dashed line.

5 A relatively small, regulated amount of anaesthesia-inducing medication is given to the patient for a brief period of time t_1 - t_2 in order to keep the patient at the desired depth of anaesthesia or for controlled regulation of the depth of anaesthesia.

10 The possibility of supplying medication in an amount and at a rate consistent with empirical values while using values for patient criteria for regulating the period from t_1 to t_2 also falls within the scope of the invention.

 The "successive" administration of medication or agents means that an empty container (11a) is refilled with a given amount ($1/2$). This amount is emptied and then refilled to a lesser degree ($1/4$) etc.

15 The invention is clearly not limited to the exemplary embodiments above but can be modified within the scope of the invention concept as illustrated in the following patent claims.

PATENT CLAIMS

- 1 A system for controllably regulating the administration of fluid medication to a patient to be anaesthetised with intravenous anaesthesia, the said system
5 comprising at least one container for the fluid medication, a circuit for regulating the volume of medication delivered to the said patient per unit of time and a tube between the said circuit or container and the said patient, a connection arrangement being provided to allow the passage of medication from the said container to the patient, **characterized** in that the said connection arrangement is in the form
10 of a filter devised to separate multi-patient parts and accessories from single-patient parts and accessories, and the said filter is devised to form an interface preventing contaminating particles from migrating into the former parts and accessories.
- 15 2. The system according to claim 1, **characterized** in that the said connection arrangement, and/or some other and/or some additional coupling arrangement arranged in the direction of flow, is devised to prevent small contaminating particles from migrating into the said container during the normal flow of medication in one direction, and the said connection arrangement is arranged to keep residual
20 volume small.
- 25 3. The system according to claim 2, **characterized** in that the container is subdivided into at least two parts, i.e. a container in an infusion unit and a reserve container connected or adjacent to the said container.
- 30 4. The system according to claim 2 or 3, **characterized** in that the infusion unit container has a connector, arranged close to the outlet for or consisting of an outlet for medication, through which medication is filled.
5. The system according to patent claim 3 or 4, **characterized** in that a control unit in an infusion unit is devised to empty the contents of the infusion unit container and then transfer small amounts of anaesthesia-inducing medication from the reserve container in order to keep residual volume small.

6. The system according to any of claims 3-5, **characterized** in that a valve arrangement, containing at least one one-way valve, is arranged between the container and reserve container.
- 5 7. The system according to any of claims 1,2 or 3-6, **characterized** in that the said filters, devised to prevent bacteria, viruses and similar contaminating particles from reaching medication in the reserve container, are arranged between the container and the reserve container.
- 10 8. The system according to claim 2, **characterized** in that a valve is arranged between the reserve container and the connection arrangement.
9. The system according to claim 2 or 3, **characterized** in that the reserve container is a rigid container.
- 15 10. The system according to claim 2 or 3, **characterized** in that the reserve container is a flexible container.
11. The system according to claim 9, **characterized** in that the said connection arrangement has an arrangement for sending air to the reserve container.
- 20 12. The system according to claim 9, **characterized** in that the connection arrangement is divided into two parts, i.e. a medication passage and an air passage, a filter, devised to block airborne bacteria, viruses and similar contaminating particles, being arranged in the air passage.
- 25 13. The system according to claim 1, **characterized** in that an infusion unit container has a first volume selected to correspond to the volume of medication needed during an initial phase for inducing a desired depth of anaesthesia in the patient.
- 30 14. The system according to claim 13, **characterized** in that the infusion unit is devised to deliver, after the initial phase, smaller amounts of medication per unit

of time in order to keep the patient within suitable limits for the depth of anaesthesia.

15. The system according to claim 13, **characterized** in that a three-way connector is connected to the container, reserve container and patient tube, and one-way valves are arranged in a line to the reserve container and tube.

16. The system according to claim 15, **characterized** in that a reserve container one-way valve is devised to permit the passage of medication only at a pressure exceeding a pre-selected value, i.e. somewhat higher than hydrostatic pressure from the reserve container.

17. The system according to claim 1 or 16, **characterized** in that a filter is arranged upstream from a one-way valve.

18. The system according to claim 1, 16 or 17, **characterized** in that a one-way valve is arranged upstream from the said filter.

19. The system according to claim 18, **characterized** in that a shut-off and/or opening valve is arranged upstream from the said one-way valve.

20. The system according to claim 1 or 15, **characterized** in that a one-way valve and a filter are conjoined and/or located near each other.

21. The system according to claim 1 or 15, **characterized** in that the said interface is arranged between the three-way connector and the one-way valve.

22. The system according to claim 1 or 15, **characterized** in that the said interface is arranged upstream from the filter.

23. The system according to claim 1 or 15, **characterized** in that the said interface is arranged next to the reserve container.

24. The system according to claim 1, **characterized** in that an infusion unit container has a second volume, smaller than a first volume, for initially inducing a desired depth of anaesthesia in a patient, by employing a selected number of emptyings and fillings of the said second volume during an initial phase in order to induce a desired depth of anaesthesia in a patient.

25. The system according to claim 24, **characterized** in that the infusion unit is devised to deliver, after the initial phase, a smaller amount of medication per unit of time in order to keep the patient within suitable limits for the desired depth of anaesthesia.

26. The system according to claim 1, **characterized** in that the tube is connected to the filter, and the interface is arranged downstream and/or upstream from the said filter.

27. The system according to claim 1 or 26, **characterized** in that the regulatory circuit consists e.g. of a piston-cylinder arrangement with a one-way valve on each side, and the piston's reciprocal movements are controlled by a control circuit in an infusion unit.

28. The system according to claim 27, **characterized** in that the said piston-cylinder arrangement and the said one-way valves are conjoined in a single unit whose external shape fits the shape of an infusion unit recess devised for a container.

29. The system according to claim 27 or 28, **characterized** in that a filter is arranged upstream and/or downstream from the said unit.

30. The system according to claim 29, **characterized** in that the said interface is arranged downstream and/or upstream from the said filter.

31. The system according to claim 1, **characterized** in that the tube is arranged between a large-volume container, through one or more filters and a medication regulating circuit, and a cannula or the like.

32. The system according to claim 31, **characterized** in that the said circuit is devised to have the control unit choke off and/or open a section of tube, by means of a plate or the like, in order to regulate the administration of medication.

5 33. The system according to claim 31, **characterized** in that the said filter is arranged downstream and/or upstream from the said circuit.

34. The system according to claim 1 or 33, **characterized** in that the said interface is arranged downstream and/or upstream from the said filter.

10

35. The system according to claim 31, **characterized** in that the medication-regulating circuit is devised to control the administration of medication solely on the basis of patient-related criteria.

15 36. The system according to claim 32, **characterized** in that the administration of medication is arranged to take place from a container located above the level of the patient.

20 37. The system according to claim 31, **characterized** in that the said circuit is devised to have the control unit, by means of a pump or similar means on the tube periphery, choke off and/or open a section of tube in order to regulate the administration of medication.

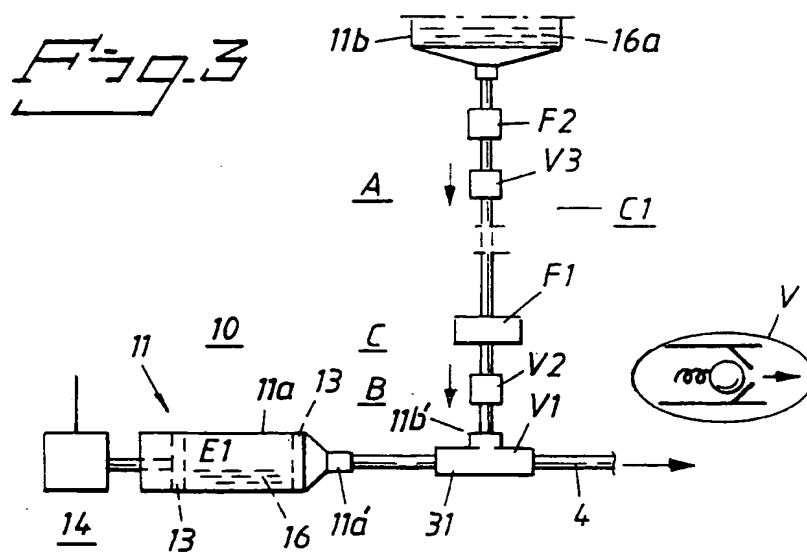
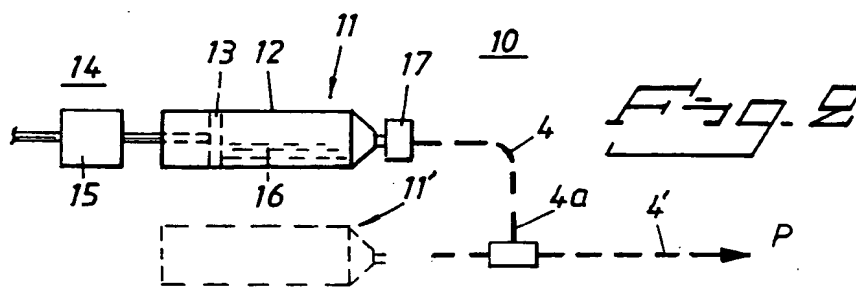
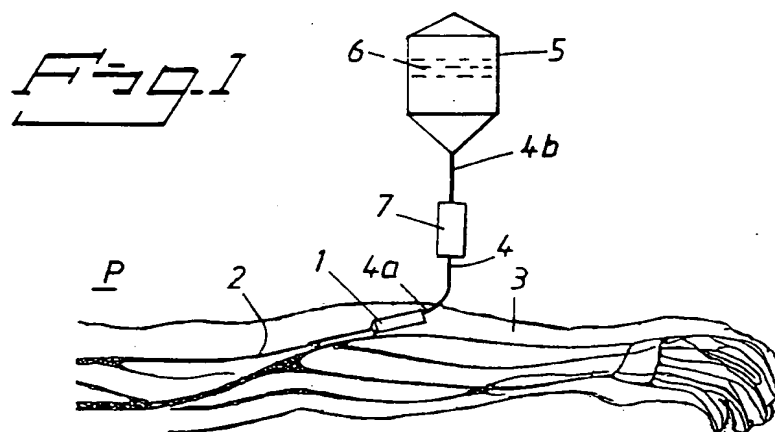
25 38. The system according to claim 37, **characterized** in that one or more filters are arranged downstream and/or upstream from the said pumping unit.

39. The system according to claim 37, **characterized** in that an interface is arranged downstream and/or upstream from a filter.

30 40. The system according to claim 37, **characterized** in that a medication-regulating circuit is arranged to control the administration of medication on the basis of patient-related criteria, e.g. on the basis of information on the volume of medication supplied per unit of time.

41. The system according to claim 37, **characterized** in that the administration of medication is arranged to take place from a container located above the level of the patient.

1 / 2



2 / 2

Fig. 4

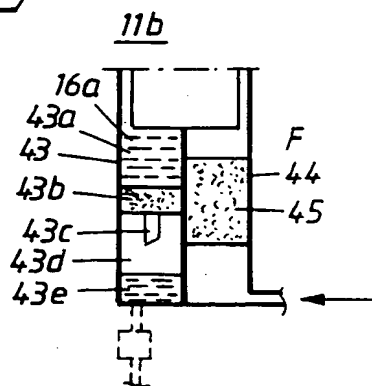


Fig. 5

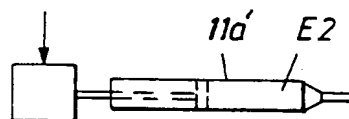


Fig. 7

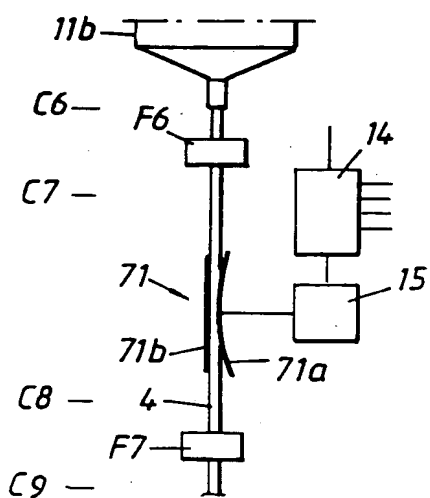


Fig. 6

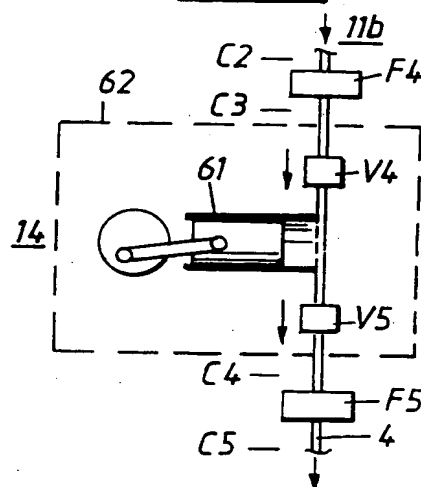


Fig. 8

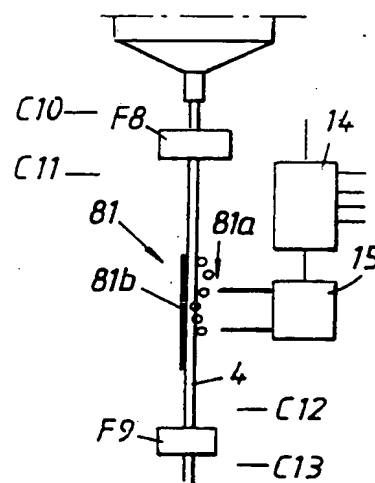
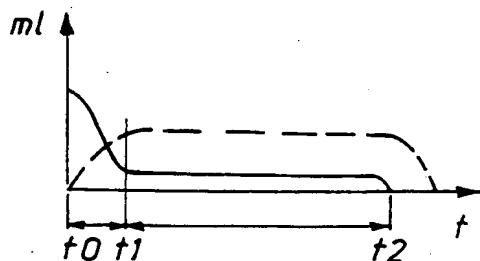


Fig. 9



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/02222

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/14, A61M 5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9110861 A1 (PATTULLO,NORMAN), 25 July 1991 (25.07.91), page 10, line 23 - page 12, line 24	1-3,6-10,13, 20-25,33-36, 38-41
A	--	12,27-30
X	US 5916201 A (R.B.WILSON,JR ET AL), 29 June 1999 (29.06.99), column 3, line 36 - line 60, figures 1, 9	4,14-16,18, 26,31-32,37
X	US 5968014 A (F.NEFTEL ET AL), 19 October 1999 (19.10.99), column 2, line 43 - line 52; column 4, line 17 - line 26; column 7, line 39 - line 43, figures 2,3	5,11,17,19
	-- -----	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

13 March 2001

Date of mailing of the international search report

14 -03- 2001

Name and mailing address of the ISA/

Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

Ulrika Andersson /itw

Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

25/02/01

International application No.

PCT/SE 00/02222

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
WO	9110861	A1	25/07/91	AT	127894 T	15/09/95
				AU	654806 B	24/11/94
				AU	7051491 A	05/08/91
				CA	2074071 A	19/07/91
				DE	69022431 D,T	02/05/96
				DK	511241 T	29/01/96
				EP	0511241 A,B	04/11/92
				SE	0511241 T3	
				ES	2079639 T	16/01/96
				FI	98090 B,C	31/12/96
				FI	913912 D	00/00/00
				FI	923303 A	20/07/92
				GR	3018292 T	31/03/96
				HK	1497 A	10/01/97
				NO	304393 B	07/12/98
				NO	922875 D	00/00/00
				US	5364377 A	15/11/94
US	5916201	A	29/06/99	AU	708745 B	12/08/99
				AU	4964296 A	07/08/96
				EP	0805694 A	12/11/97
				JP	11503926 T	06/04/99
				NO	973249 A	11/07/97
				NZ	303355 A	19/12/97
				CA	2204185 A	25/07/96
				US	5540668 A	30/07/96
				WO	9622118 A	25/07/96
US	5968014	A	19/10/99	AU	700190 B	24/12/98
				AU	6878196 A	19/03/97
				CA	2227973 A	06/03/97
				CN	1193919 A	23/09/98
				CZ	9800561 A	15/07/98
				EP	0846008 A	10/06/98
				HU	9901390 A	30/08/99
				JP	11511346 T	05/10/99
				NO	980774 A	24/04/98
				PL	325202 A	06/07/98
				WO	9707842 A	06/03/97

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.